APR 17 2013

Section 5.0 510(k) Summary

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Contact Persons:	Nora O'Connor, Regulatory Affairs Specialist Sinead Burke, Regulatory Affairs Manager
Date:	September 03, 2012
Trade Name:	Plasmatrode™ Saline Safe TUR Electrode
Common Name:	Vaporization and Coagulation Electrode
Classification Name:	Electrosurgical, Cutting & Coagulation & Accessories (21 CFR 878.4400, Product Code: GEI)
Predicate Devices:	COOK® Single-Use RF Electrode (COOK® Coagulator Probe, K935874), Gyrus PK® Plasma V™ Vaporization Electrode (K990628 - Gyrus Endourology System) and the Olympus PK® Plasmabutton™ Vapourization Electrode (K100275 and K102781 - HF-Resection and Vaporization Electrode Series).
Description of the Device:	The Plasmatrode™ Saline Safe TUR Electrode (also known as the Plasmatrode™) is a monopolar electrode used to deliver radio frequency energy supplied by a general purpose electrosurgical generator for the purpose of vaporization and coagulation of soft prostatic tissue during the treatment of Benign Prostatic Hyperplasia (BPH). The Plasmatrode™ comprises of the following: - A tip assembly, which in turn consists of an active electrode, a tip insulator and a floating electrode.

- Ceramic shields
- A conductive shaft
- Insulating heat shrink

The Plasmatrode™ is compatible for use with ACMI USA/Elite, Olympus OES and Karl Storz Single Stem and Double Stem resectoscopes.

Indications for use: This device is used to vaporize and coagulate soft prostatic tissue during the treatment of Benign Prostatic Hyperplasia and for use with a compatible resectoscope.

Comparison of Characteristics: The Plasmatrode™ is substantially equivalent to the currently marketed predicate devices, COOK® Single-Use RF Electrode (COOK® Coagulator Probe, K935874), Gyrus PK® Plasma V™ Vaporization Electrode (K990628 - Gyrus Endourology System) and the Olympus PK® Plasmabutton™ Vapourization Electrode (K100275 and K102781 - HF-Resection and Vaporization Electrode Series).

The proposed device shares many technological characteristics with at least one of the predicate devices (or fall within the range of predicates) in terms of the following:

- Energy Type
- FDA Classification
- Tip Design
- Tip materials
- Conductive Shaft
- Device Length
- Polarity
- Irrigant
- Resectoscope Compatibility
- Intended Use
- All devices are intended for single use and are supplied sterile
- Endoscopically used
- Electrosurgically used

Differences include:
Tip width
Distal end to conductive shaft design and materials

Performance Data: Performance testing was carried out to determine the substantial equivalence of the Plasmatrode™ and to verify the safety and effectiveness of the device.

Performance Testing-Bench and Animal:

The bench testing was conducted in accordance with various applicable ASTM standards and in accordance with FDA's *Guidance for the Non-Clinical and Clinical Investigations of Devices used for the Treatment of Benign Prostatic Hyperplasia (BPH)* (August 17, 2010). The following tests were carried out: electrosurgical safety testing, simulated use (reliability/activation testing), resectoscope interaction, tensile testing, shelf life testing and animal testing. The performance testing was successfully completed. Results of the testing provide reasonable assurance that the Plasmatrode™ Saline Safe TUR Electrode will function as intended.

Biocompatibility:

Biocompatibility testing in compliance with ISO 10993-1, and FDA's *Guidance for the Non-Clinical and Clinical Investigations of Devices used for the Treatment of Benign Prostatic Hyperplasia (BPH)* (August 17, 2010) supports the safety of the Plasmatrode™.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 17, 2013

Cook Ireland Ltd.
% Ms. Nora O'Connor
Regulatory Affairs Specialist
O'Halloran Road, National Technology Park
LIMERICK
IRELAND

Re: K122716
Trade/Device Name: Plasmatrode™ Saline Safe TUR Electrode
Regulation Number: 21 CFR§ 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: March 7, 2013
Received: March 11, 2013

Dear Ms. O'Connor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4.0 Indications for Use

510(k) Number (if known): K122716

Device Name: Plasmatrode™ Saline Safe TUR Electrode

Indications for Use:

This device is used to vaporize and coagulate soft prostatic tissue during the treatment of Benign Prostatic Hyperplasia and for use with a compatible resectoscope.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
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(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K122716